



Practice r's Dock t N . 6029-2669

**PATENT**

GP 1646  
TJP  
TJZ

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Patent application

of \_\_\_\_\_ Inventor(s)

for \_\_\_\_\_ Title of invention

the specification of which is being transmitted herewith

OR

In re application of: Eugene M. Johnson et al.

Application No.: 09 /476,290 Group No.:

Filed: December 30, 1999 Examiner:

For: NEURTURIN AND RELATED GROWTH FACTORS

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Assistant Commissioner for Patents

Washington, D.C. 20231

**INFORMATION DISCLOSURE STATEMENT**

**CERTIFICATION UNDER 37 C.F.R. §§ 1.8(a) and 1.10\***

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Express Mail certification is optional.)

I hereby certify that, on the date shown below, this correspondence is being:

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*Elie H. Gendloff*  
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Date: March 31, 2000

Elie H. Gendloff  
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\*WARNING: Each paper or fee filed by Express Mail **must** have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. § 1.10(b).

"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will **not** be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

(Information Disclosure Statement [6-1]—page 1 of 7)

**NOTE:** "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 CFR 1.56(a).

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) each inventor named in the application;
- (2) each attorney or agent who prepares or prosecutes the application; and
- (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 CFR 1.56(c).

**NOTE:** The "duty as described in § 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b) - (d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O.G. 13 -25 at 17.

**WARNING:** "No information disclosure statement may be filed in a provisional application." 37 CFR § 1.51(b).

### **List of Sections Forming Part of This Information Disclosure Statement**

The following sections are being submitted for this Information Disclosure Statement:

*(check sections forming a part of this statement: discard unused sections  
and number pages consecutively)*

1.  Preliminary Statements
2.  FORM PTO - 1449 (Modified)
3.  Statement as to Information Not Found in Patents or Publications
4.  Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
5.  Cumulative Patents or Publications
6.  Copies of Listed Information Items Accompanying This Statement
7.  Concise Explanation of Non-English Language Listed Information Items
  - 7A.  EPO Search Report
  - 7B.  English Language Version of EPO Search Report
8.  Translation(s) of Non-English Language Documents
9.  Concise Explanation of English Language Listed Information Items (Optional)
10.  Identification of Person(s) Making This Information Disclosure Statement

*(complete the following, if appropriate)*

Sections 2, 4, 6 and 10, respectively, have been continued on ADDED PAGE(S).

**NOTE:** "Once the minimum requirements are met, the examiner has an obligation to consider the information." Notice of April 20, 1992 (1138 O.G. 37-41, 37).

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**S e c t i o n 4. I d e n t i f i c a t i o n o f P r i o r A p p l i c a t i o n i n W h i c h L i s t e d I n f o r m a t i o n  
W a s A l r e a d y C i t e d a n d f o r W h i c h N o C o p i e s A r e S u b m i t t e d o r  
N e e d e d t o b e S u b m i t t e d**

**NOTE:** "A copy of any patent, publication or other information listed in an information disclosure statement is not required to be provided if it was previously cited by or submitted to the Office in a prior application, provided that the prior application is properly identified in the statement and relied upon for an earlier filing date under 35 U.S.C. 120." 37 C.F.R. § 1.98(d).

**WARNING:** "This exception to the requirement for copies of information does not apply to information which was cited in an international application under the Patent Cooperation Treaty." Notice of April 20, 1992 (1138 O.G. 37-41, 38).

**WARNING:** "Information which is cited or submitted to the Office in the parent application of a file wrapper continuing application under 37 C.F.R. 1.62 will be part of the file before the examiner and need not be resubmitted in the continuing application. Likewise, the examiner will consider information cited or submitted to the Office in a parent application when examining a continuing application and thus this information need not be resubmitted unless applicant desires the information to be printed on the patent." Notice of April 20, 1992 (1138 O.G. 37-41, 37).

**WARNING:** While a copy of a non-English language item of information need not be submitted, if it was previously submitted to, or cited by, the Office in a prior application, provided it is properly identified in this statement and this application relies on that earlier filing date under 35 U.S.C. 120, nevertheless, the requirement in § 1.98(a)(3) for a concise explanation of non-English language information would not be satisfied by a statement that a reference was cited in the prosecution of a parent application. The concise explanation must explain the relevance, as presently understood by the person designated in § 1.56(c) most knowledgeable about the content of the information. Notice of January 9, 1992, 1135 O.G. 13-25, at 20.

This application relies, under 35 U.S.C. § 120, on the earlier filing date of prior application SN.: 08 / 981,738, filed on April 13, 1998 (date).

(complete the following, if applicable)

This application also relies, under 35 U.S.C. 120, on the earlier filing date of prior application SN.: 08 / 519,777, filed on August 28, 1995 (date).

The following references were submitted to, and/or cited by, the Office in the prior application(s) and, therefore, are not required to be provided in this application:

See Attached PTO Form 1449

## **Section 6. Copies of Listed Information Items Accompanying This Statement**

*NOTE: 37 C.F.R. 1.98(a)(2) requires that any information disclosure statement filed under § 1.97 shall include: "A legible copy of: (1) Each U.S. and foreign patent; (ii) Each publication or that portion which caused it to be listed; and (iii) All other information or that portion which caused it to be listed, except that no copy of a U.S. patent application need be included . . . "*

*NOTE: The wording in § 1.98(a)(2)(iii) makes it clear that the requirement to submit a copy of each item of information listed in an information disclosure statement does not apply to the citation of a U.S. patent application. Notice of January 9, 1992, 1135 O.G. 13-25, at 14.*

Legible copies of all items listed in Forms PTO/SB/08A and 08B (formerly Form PTO-1449) accompany this information statement.

*(complete the following, if applicable)*

Exception(s) to above:

- Items in prior application, from which an earlier filing date is claimed for this application, as identified in Section 4.
- Cumulative patents or publications Identified in Section 5.

**Secti n 10. Identificati n of Pers n(s) Making Thi Inf rmati n  
Disclosur Stat ment**

The person making this statement is

(check each applicable item)

(a)  the inventor(s) who signs below

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**SIGNATURE OF INVENTOR**

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(type name of inventor who is signing)

(b)  an individual associated with the filing and prosecution of this application (37 C.F.R. § 1.56(c))

---

**SIGNATURE OF INVENTOR**

---

(type name of inventor who is signing)

(c)  the practitioner who signs below on the basis of the information:

(check each applicable item)

supplied by the inventor(s).  
 supplied by an individual associated with the filing and prosecution of this application. (37 C.F.R. § 1.56(c))  
 in the practitioner's file.

---

  
**SIGNATURE OF PRACTITIONER**

---

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(type or print name of practitioner)

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Customer No.:

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LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT					ATTORNEY'S DOCKET NO.: 6029-2669		
Applicant: Johnson et al.		Serial No.: 09/476,290		Filing Date: December 30, 1999	Group Art Unit: Unknown		
<b>U.S. PATENT DOCUMENTS</b>							
Examiner Initial		Document Number:	Date:	Name:	Class:	Sub-Class:	Filing Date:
	AA	5,011,914	04/30/91	Collins et al.			
	AB	5,141,856	08/25/92	Collins et al.			
	AC	5,235,043	08/10/93	Collins et al.			
	AD	5,260,417	11/9/93	Grant et al.			
<b>FOREIGN PATENT DOCUMENTS</b>							
		Document Number:	Date:	Country:	Class:	Sub-Class:	Translation:
	AE	WO 93/0616	04/01/93	PCT			No English
	AF	WO 95/06662	03/09/95	PCT			No English
<b>OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, etc.)</b>							
	AG	Baringa, Neurotrophic Factors Enter the Clinic, <i>Science</i> 264:772-774 (1994)					
	AH	Beutler et al., Hematology, USA:McGraw-Hill Inc., 5th Ed. pp 221-248, 456, 467-468, 821-822, 850, 879, 965-966, 1276-1287 (1995)					
	AI	Bowenkamp et al. Glial Cell Line-Derived Neurotrophic Factor Supports Survival of Injured Midbrain Dopaminergic Neurons, <i>J. Comp. Neuro.</i> 355:470-89 (1995)					
	AJ	Buj-Bello et al., GDNF is an Age-Specific Survival Factor for Sensory and Autonomic Neurons, <i>Neuron</i> 15:821-8 (1995)					
	AK	Cheng et al., NGF and bFGF Protect Rat Hippocampal and Human Cortical Neurons Against Hypoglycemic Damage by Stabilizing Calcium Homeostasis, <i>Neuron</i> 1:1031-41 (1991)					
	AL	Hall, IL-12 at the Crossroads, <i>Science</i> 268:1432-1434 (1995)					
	AM	Henderson et al., GDNF: A Potent Survival Factor for Motoneurons Present in Peripheral Nerve and Muscle, <i>Science</i> 266:1062-4 (1994)					
	AN	Jackowski, A Neural injury repair: hope for the future as barriers to effective CNS regeneration become clearer, <i>British Journal Of Neurosurgery</i> 9:303-317 (1995)					
	AO	Kearns et al., GDNF Protects Nigral Dopamine Neurons Against 6-Hydroxydopamine <i>in vivo</i> , <i>Brain Research</i> 672:104-11 (1995)					
	AP	Kingsley The TGF- $\beta$ Superfamily: New Members, New Receptors, and New Genetic Tests of Function in Different Organisms, <i>Genes and Dev.</i> 8:133-46 (1994)					
	AQ	Klein, Role of Neurotrophins in Mouse Neuronal Development, <i>FASEB J.</i> 8:738-44 (1994)					
	AR	Kotzbauer et al., Postnatal Development of Survival Responsiveness in Rat Sympathetic Neurons to Leukemia Inhibitory Factor and Ciliary Neurotrophic Factor, <i>Neuron</i> 12:763-73 (1994)					
	AS	Liebrock et al., Molecular Cloning and Expression of Brain-Derived Neurotrophic Factor, <i>Nature</i> 341:149-52 (1989)					

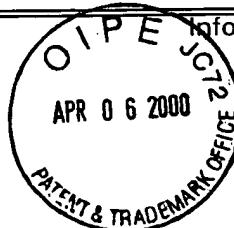
	AT	Lin et al., Purification, Cloning, and Expression of Ciliary Neurotrophic Factor (CNTF), <i>Science</i> 246:1023-5 (1989)
	AU	Lin et al., GDNF: A Glial Cell Line-Derived Neurotrophic Factor for Midbrain Dopaminergic Neurons, <i>Science</i> 260:1130-2 (1993)
	AV	Levi-Montalcini et al., Selective Growth Stimulating Effects of Mouse Sarcoma on the Sensory and Sympathetic Nervous System of the Chick Embryo, <i>J. Exp. Zool.</i> 116:321-61 (1951)
	AW	Oppoenheim et al., Developing Motor Neurons Rescued from Programmed and Axotomy-Induced Cell Death by GDNF, <i>Nature</i> 373:344-6 (1995)
	AX	Stratagene Catalog, pp 154-159 (1994)
	AY	Trupp et al., Peripheral Expression and Biological Activities of GDNF, a New Neurotrophic Factor for Avian and Mammalian Peripheral Neurons, <i>J. Cell. Biol.</i> 130:137-48 (1995)
	AZ	Tuszynski et al., Neurotrophic Factors and Diseases of the Nervous System, <i>Ann. Neurol.</i> 35:S9-S12 (1994)
	BA	Yan et al., <i>In Vivo</i> Neurotrophic Effects of GDNF on Neonatal and Adult Facial Motor Neurons, <i>Nature</i> 373:341-4 (1995)

EXAMINER:

DATE CONSIDERED:

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of the form with next communication to applicant.

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Information Disclosure Statement -- PTO-1449 (Modified)